cGMP Process Development Specialist
Job Description

JOB INFORMATION

Job Code:	188005
Job Title:	cGMP Process Development Specialist
FLSA Status:	Exempt
Supervisory:	May lead one or more employees performing similar work.
Job Family:	Clinical Research
Job Family Group:	USC Job Families
Management Level:	7 Individual Contributor

JOB SUMMARY

Responsible for developing the manufacturing process of multiple cell-based products based on current Good Manufacturing Practice (cGMP) design considerations (e.g., assay development and qualification). Supports technology transfer activities from laboratory to GMP manufacturing. Establishes vector manufacturing platform.

JOB QUALIFICATIONS:

Education

Req	*Pref*	*Degree*	*Field of Study*	
X		Master's degree		Or
X		Master's degree	Pharmacy	Or
X		Master's degree	Biology	Or
X		Master's degree	in related field(s)	
	X	Doctorate	Biotechnology	Or
	X	Doctorate	in related field(s)	

Additional Education

Check here if experience may substitute for some of the above education.

	Combined experience/education as substitute for minimum education

Work Experience

Req	*Pref*	*Work Experience*	*Experience Level*	
X		3 years	in cellular or biological manufacturing and with process development and analytical methods	

Additional Work Experience

Check here if education may substitute for some of the above work experience.

	Combined experience/education as substitute for minimum work experience

Knowledge, Skills and Abilities

Req	Pref	Functional Skills
X		Experience manufacturing scale processes using various cell culture platforms (e.g. Cell Factories, G-Rex's, Bioreacotrs) and equipment (e.g., CliniMACS Prodigy, CliniMACS Plus, LOVO).
X		Demonstrated knowledge base with Good Manufacturing Practices (e.g., cGMPs, GLPs, GDPs).
X		Experience with standard operating procedures in a cGMP laboratory setting.
X		Demonstrated ability to work as an individual contributor and in a dynamic team environment.
X		Excellent written and oral communication skills.
	X	Demonstrated knowledge of all aspects of biotechnology and cell therapy.
	X	Demonstrated passion for solving complex scientific issues.
	X	Experience with Food and Drug Administration regulations and clinical trials.
	X	Extensive leadership experience.

Other Job Factors

JOB ACCOUNTABILITIES

	% Time	Essential	Marginal	N/A
Responsible for leading process development, optimization and scale-up activities for the manufacture of cell therapies and biologics. Establishes and executes development project plans (e.g., process and assay development, assay qualification, support tech transfer of processes) from cGMP manufacturing and assays to quality control. Develops and reviews standard operating procedures (SOP), protocols and process development and technical reports.				
Sets up labs for process development work (e.g., purchases and installs equipment, establishes lab SOP). Participates in vendor management and qualification visits as needed.				
Provides technical direction and training for process development activities based on clinical manufacturing and cGMP design consideration. Serves as a resource to cGMP facility management in identifying and assessing the appropriate complement of resources and support needed to successfully implement and execute projects. Provides training support to the manufacturing and quality control teams during tech transfer.				
Designs and produces viral vectors, and characterizes them by performing varied in vitro and in vivo assays. Supports in-process testing, product characterization, final product release and comparability testing. Generates Chemistry, Manufacturing, and Control (CMC) documents for Investigational New Drug (IND) applications. Generates validation plans for new products. Works with senior staff to ensure facilities' compliance with all applicable regulations.				
Designs, executes, summarizes and presents process development studies while maintaining good documentation practices. Performs gap analyses and risk assessments to identify problems and deficiencies. Provides recommendations for studies and solutions to manufacturing process issues. Attends routine meetings with management team for progress reports on projects, facility needs, and discussion of any other required items.				
Promotes an environment that fosters inclusive relationships and creates unbiased opportunities for contributions through ideas, words, and actions that uphold principles of the USC Code of Ethics.				

Other Requirements

Essential:	Emergency Response/Recovery	Essential:	Mandated Reporter
	In the event of an emergency, the employee holding this position is required to "report to duty" in accordance with the university's Emergency Operations Plan and/or the employee's department's emergency response and/or recovery plans. Familiarity with those plans and regular training to implement those plans is required. During or immediately following an emergency, the employee will be		A mandated reporter who in his or her professional capacity has knowledge of, or reasonably suspects a person who is under the age of 18 years, elderly, or a dependent adult has been the victim of abuse or neglect must report the suspected incident. The reporter must contact a designated agency immediately or as soon as practically possible by telephone or in writing within 36 hours. By virtue of the associated job duties, this position qualifies

Other Requirements

Essential:	*Emergency Response/Recovery*	*Essential:*	*Mandated Reporter*
	notified to assist in the emergency response efforts, and mobilize other staff members if needed.		as a mandated reporter as required by state law and USC's policy at: https://policy.usc.edu/mandated-reporters/

Campus Security Authority (CSA)	*Essential:*
By virtue of the associated job duties, this position qualifies as a Campus Security Authority as required by law and USC's policy at: https://dps.usc.edu/alerts/clery/	

ACKNOWLEDGMENTS

The above statements reflect the essential and non-essential functions as necessary to describe the principle contents of the job. They are not intended to be a complete statement of all work requirements or duties that may be required of the position. I understand that I may be asked to perform other duties as assigned. USC reserves the right to add or change duties at any time.

The University of Southern California is an Equal Opportunity Employer. USC prohibits discrimination on any basis protected under federal, state, or local law, regulation, or ordinance or university policies. All employment decisions are based on individual qualifications and business need.

I acknowledge receipt of this job description and its associated physical requirements. I have read and understand the job description and job requirements and agree to abide by their contents. I realize that duties may be requested of me that are not specifically stated herein. I understand that I will be expected to adjust to potential fluctuations in work volume. I understand that, if I have any questions about the essential functions or expectations of my position, my supervisor and/or HR partner are available to discuss them with me.

_____	_____	_____
Print Employee Name	Signature	Date
_____	_____	_____
Print Manager Name	Signature	Date

This job description describes the general nature and level of work required by the position. It is not intended to be an all-inclusive list of qualifications, skills,
duties, responsibilities or working conditions of the job. The job description is subject to change with or without notice, and Management reserves the right to add, modify or remove any qualification or duty. Nothing in this job description changes the existing at-will employment relationship between the university and the employee occupying the position.